

LISTING OF THE CLAIMS

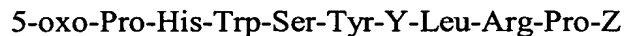
No amendments have been made to the claims. This listing of the claims is being provided solely for the convenience of the Examiner.

Listing of Claims:

1-15. (Canceled).

16. (Previously presented) A sustained release preparation comprising a combination of first microcapsules which gradually release a GnRH agonist or a salt thereof for 5 months or longer, and second microcapsules which gradually release a GnRH agonist or a salt thereof for shorter than 5 months so that blood concentration of the GnRH agonist within one week after administration is about 2 ng/mL or higher.

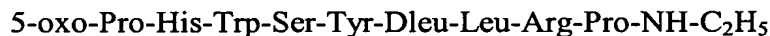
17. (Previously presented) The preparation according to claim 16, wherein the GnRH agonist or a salt thereof is a peptide represented by the formula of SEQ ID NO: 1:



wherein Y represents a residue selected from DLeu, DAla, DTrp, DSer (tBu), D2Nal and DHis (ImBzl), and Z represents NH-C₂H₅ or Gly-NH₂

or a salt thereof.

18. (Previously presented) The preparation according to claim 16, wherein the GnRH agonist or a salt thereof is an acetate of a peptide of the formula of SEQ ID NO: 2:



19. (Canceled)

20. (Previously presented) The preparation according to claim 16, wherein the long term is 5 months or longer and 8 months or shorter, and the short term is 1 week or longer and shorter than 5 months.

21. (Previously presented) The preparation according to claim 16, wherein the microcapsules comprise a lactic acid polymer or a lactic acid-glycolic acid polymer.

22. (Previously presented) The preparation according to claim 16, wherein the ratio of first microcapsules to second microcapsules is from 5:1 to 20:1 expressed as weight ratios of the GnRH agonist or a salt thereof.
23. (Previously presented) The preparation according to claim 16, wherein:
- (a) the first microcapsules comprise:
 - (i) a GnRH agonist or a salt thereof, and
 - (ii) a lactic acid polymer having a weight-average molecular weight of about 18,000 to about 30,000; and
 - (b) the second microcapsules comprise:
 - (i) a GnRH agonist or a salt thereof, and
 - (ii) a lactic acid-glycolic acid polymer (75/25 (mol %)) having a weight-average molecular weight of 3,000 to about 12,000, or a lactic acid polymer having a weight-average molecular weight of about 13,000 to about 18,000.
24. (Previously presented) The preparation according to claim 16, wherein:
- (a) the first microcapsules comprise:
 - (i) a GnRH agonist or a salt thereof, and
 - (ii) a lactic acid polymer having a weight-average molecular weight of about 15,000 to about 50,000 in which a content of a polymer having a weight-average molecular weight of 5,000 or less is about 5% or less by weight; and
 - (b) the second microcapsules:
 - (1) comprise (i) a GnRH agonist or a salt thereof, and (ii) a lactic acid-glycolic acid polymer in which a weight-average molecular weight (Mw) is about 8,000 to about 11,500, and a ratio of a weight-average molecular weight (Mw) to a number-average molecular weight (Mn) is greater than 1.9, and a compositional molar ratio of lactic acid to glycolic acid is 99.9/0.1 to 60/40, and which does not contain a drug retaining substance,

or

(2) zero order-release a GnRH agonist or a salt thereof over 2 months, and are prepared by microencapsulating a W/O emulsion prepared from an inner aqueous phase solution containing a GnRH agonist or a salt thereof in about 20 to 70% by weight, and an oil phase solution containing, as a release controlling substance, a copolymer or a homopolymer in which a compositional ratio of lactic acid/glycolic acid is 80/20 to 100/0, and a weight-average molecular weight is about 7,000 to about 30,000.

25. (Previously presented) The sustained-release preparation according to claim 16, which gradually releases a substantially constant amount of a GnRH agonist or a salt thereof for 5 months or longer.

26. (Canceled)

27. (Previously presented) A composition comprising:

(a) a pharmaceutically effective amount for preventing or treating prostate cancer, prostatomegaly, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or breast cancer, or for contraception of the sustained-release preparation according to claim 16, and

(b) a pharmaceutically acceptable excipient.

28. (Previously presented) A process for producing the sustained-release preparation according to claim 16, which comprises mixing the first and second microcapsules.

29. (Previously presented) A method comprising administering an effective amount for preventing or treating prostate cancer, prostatomegaly, endometriosis, hysteromyoma, metrofibroma, precocious puberty, dysmenorrhea or breast cancer, or preventing conception of the sustained-release preparation according to claim 16 to a mammal in need thereof.

30. (Previously presented) The preparation according to claim 16, wherein:

(a) the first microcapsules comprise:

(i) a GnRH agonist or a salt thereof, and

(ii) a lactic acid polymer having a weight-average molecular weight of about 21400; and

(b) the second microcapsules:

- (1) comprise (i) a GnRH agonist or a salt thereof, and (ii) a lactic acid-glycolic acid polymer (75/25 (mol%)) having a weight-average molecular weight of about 10400,
or
- (2) comprise (i) a GnRH agonist or a salt thereof, and (ii) a lactic acid polymer
having a weight-average molecular weight of about 14200.